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AgrEvo

DATA EVALUATION REPORT

Reviewed by: John L. Kough, Ph.D., Biologist, BPPD JLK

Secondary Reviewer: Michael Watson, Ph.D., Plant Pathologist, BPPD MW

(1P)

STUDY TYPE:	Hypersensitivity Incidence Reporting
MRID NO:	447140-03
CHEMICAL NO:	006466
TEST MATERIAL:	Cry9C protein from *Bacillus thuringiensis* ssp. *tolworthi*
STUDY NO:	none assigned
SPONSOR:	AgrEvo USA Company, Wilmington, DE
TESTING FACILITY:	Garst Seeds, Slater, IA
TITLE OF REPORT:	Occupational Exposure of StarLink™ Corn: Garst Seeds, 1996-1998
AUTHOR:	Sally Van Wert, Ph.D.
STUDY COMPLETED:	20 November 1998
CONCLUSION:	The testimonial letters submitted by employees of the Garst Seed Company indicate that 1980 people with considerable direct exposure to corn seed and plant parts including tassels and pollen have not experienced adverse or allergic responses they could directly attribute to exposure to the Cry9C protein in StarLink™ corn.
CLASSIFICATION:	Acceptable. The company is reminded that they are still responsible to report any incidents of hypersensitivity or other adverse effects they know has resulted from exposure to the Cry9C protein.

STUDY DESIGN

There is no method for this survey and the work was not done according to GLP. This is simply an accounting by the Garst Seed Company of their employees who have worked with the StarLink™ corn expressing Cry9C protein and their statements to the effect that none of them have reported adverse effects from their exposure.

The report includes thirty-four testimonial letters from people involved in various aspects of hybrid corn development such as bagging corn seed, scouting for insect damage, de-tasseling and hand pollinating. The thirty-four letters represent the responses from 1980 people. The vast majority of the people responding (1946) were found in ten letters from field production managers. The ten field production managers supervised 1936 people and reported by a form letter that they had not observed any allergic reactions to the StarLink™ corn used in hybrid production. Within the form letter is a disclaimer that "Each year we have employees that work in our fields that will have reactions to pollen dust. The reactions that we have had this year are considered normal and can not be attributed to any particular field or inbred." Also within the group of letter writers were two individuals who are atopic and reported that exposure to StarLink™ corn has not increased their level of hypersensitivity.

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